June 16, 2004

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FOOD & DRUG ADMINISTRATION
Division Of Dockets Management (HFA-305)
5630 Fishers Lane, Room 1061
Rockville, MD. 20852

RE: Medical Prescription Drug, Improvement and Modernization Act of 2003- Blind and Visually Impaired Study

Dear FDA Officials;

iVoice has become a leader in the speech recognition application development market. iVoice, Inc., designs solutions to business problems using its expertise in speech development tool and building speech based applications for the telephony markets. iVoice Inc. has achieved global recognition because of its expertise with speech recognition through the telephone. iVoice Inc., achievements have lead to increasing opportunities in both the government and commercial sectors. iVoice also develops but does not produce, voice-related technologies for medicine compliance, as well as for other products and services that may be enhanced by voice recognition and/or voice producing technology.

The basic usage under the new patent application will allow pharmacists to simply take a medication bottle and wave or run it by a designated PC. That PC, via wireless technology, will automatically download the appropriate talking prescription instructions to the pill bottle. This information comes from either what the pharmacist has typed into the computer, via text to speech, or from an existing database of instructions for the prescribed medication prepared by the pharmaceutical manufacturer. When a person cannot read or understand the label on a medication bottle, errors in use can occur. The resulting errors can range from unfavorable reactions that are simply uncomfortable to untimely death. In particular, the elderly and people with visual and other disabilities have faced serious medical emergencies because they were unable to read the labels or instructions on their medications. When it's time to take the prescription, the patient simply presses a built-in button on the medication bottle to hear the message and instructions.

In response to your request to iVoice regarding the above, we are providing the following information and thoughts, with the sections and numbered paragraphs corresponding to your numbered sections and paragraphs:

A. <u>Information About the Population of Interest</u>

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1. There are approximately 10,000,000 blind or visually impaired people in the United States, 5,500,000 of whom are age 65 or older. Of the total blind or visually impaired, about 1,300,000 are legally blind, and about 55,200 of these people are children are legally blind. About 93,600 blind or visually impaired are students who are in special education programs. About 10,800 0f these students are both deaf and blind.

2. For purposes of medicine compliance, the population may be divided into the following groupings:

    a.) Those who are blind or visually impaired and are essentially self-sufficient;
    b.) Those who are blind or visually impaired and depend upon at least one other person for essentials of life;
    c.) Those who are blind or visually impaired and who have one or more additional disabilities that require more than the assistance of another person. These may range from para- or quadriplegics, to deaf-blind or deaf-visually impaired, to terminally ill, to severe mental disabilities, or other impairment(s) requiring more than a friend or relative, e.g., a specialist, nurse, institutionalization, special equipment, etc.

B. <u>Information About the Use of Prescription Medicine</u>

1. Prescription drug information is obtained by verbal transmittal from the doctor, pharmacists or assistant, explaining from memory or reading a label or product insert. Alternatively, the blind or visually impaired relies totally on the retention of information by a relative, friend, assistant or professional assistant.

2. Education, memory and availability of help drastically affect a blind or visually impaired person's ability to comply with a prescription. This may be viewed as three separate issues:

    a.) The patient needs to understand instructions in order to follow them. This could be a broad-based (lack of) education problem, or one relating to understanding the specifics, such as timing, meals, counter indicative activity, side effects, etc.
    b.) Even when the patient understands the instructions and warnings, the patient needs to remember what the prescription and warnings are for the duration of the prescription or until it can be recommunicated by the available methodology.
    c.) Even when the patient understands and remembers all or most of the instructions, if a problem occurs, the availability of help to aide, e.g. if side effects occur or the instructions need to be

recommunicated, the blind and visually impaired obviously have special considerations.

3. Essential drug information is communicated either verbally or in Braille or via computer. Braille and computer provide permanent information sources, and are preferred. However, for example, only about 10% of legally blind children use Braille, and many are not computer literate. More appropriate and safer technology for communicating with the blind and visually impaired

4. Medication errors increase for blind and visually impaired due to the near exclusive use of memory for compliance and the lack of immediate help in reading the prescription by a third party to the patient at the time it is needed. We do not have exact statistics.

C. Information About Existing and Emerging Technologies

1. There are assistive technologies that are computer-based and are voice activated and voice responsive (speaking). It is presumed that these technologies provide access to the patient at any time so that by voice prompting, the patient may hear or rehear the instructions/warnings. However, such technologies are cost prohibitive, require software set up and recognition systems, and are not portable. The new technology of iVoice permits a blind or visually impaired person to merely press a button on the medicine container and a "speaking medicine container" will say the regimen and the warnings, repeatedly as the user may require it or may want reassurance that he/she is following the correct procedures. The basic usage of the iVoice technology covered by our new patent applications will allow pharmacists to simply take a medication bottle and wave or run it by a designated PC. That PC, via wireless technology, will automatically download the appropriate talking prescription instructions to the pill bottle. This information comes from either what the pharmacist has typed into the computer, via text to speech, or from an existing database of instructions for the prescribed medication prepared by the pharmaceutical manufacturer. When a person cannot read or understand the label on a medication bottle, errors in use can occur. The resulting errors can range from unfavorable reactions that are simply uncomfortable to untimely death. In particular, the elderly, blind people and the visually impaired have faced serious medical emergencies because they were unable to read the labels or instructions on their medications. With the iVoice system, when it's time to take the prescription, the patient simply presses a built-in button on the medication bottle to hear the message and instructions. In addition, the message prepared by the pharmaceutical manufacturer could contain additional information, including warnings, additional information regarding the condition being treated, or any other message the company wished to include to allow the company to provide

useful information and/or establish further goodwill and branding relating to its products. iVoice is hopeful that the patent application, 'Methodology for Talking Prescription Bottle with voice Instructions via Wireless Technology' will become the preferred worldwide standard for delivering prescription instructions and medication warnings to consumers. iVoice is excited about expanding the use and applications relating to speech technology by way of offering licensing to potential manufacturers.

2. Not known. Clearly, deaf/blind and handicapped with speech problems are unable to use voice activated speaking computers.

3. Not known as to computer systems, none as to the iVoice technology.

4. The new iVoice technology will drastically reduce the likelihood of compliance errors among the blind and visually impaired, and will for the first time, place them on even keel with people with sight. In other words, if people with sight need warning or compliance information, they read the label. Blind and sight impaired will have the same advantage when they merely press a button on the medicine container or cap, and it "speaks" to them!

5. Cost has not yet been determined, but once mass-produced; merely a fraction of a dollar to two dollars added cost per prescription is estimated.

6. They are not yet on the market as iVoice is currently seeking a viable licensee/manufacturer.

7. Financing is the only barrier.

8. Very practical and easy to use and much less expensive than complex computer hardware/software.

9. Eventually through marketing efforts with the blind associations and federations, United way, etc.

10. See above. Timeline for market entry depends upon funding and willing licensee/manufacturer(s).

Sincerely,

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Our Technology Speaks for Itself!™

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